Irwin Army Community Hospital and Fort Riley MEDDAC Terbinafine (Lamisil®) Prior Authorization (PA) Request Form

- To be completed, signed, and dated by the prescriber. To be used only for prescriptions filled at one of the Fort Riley MEDDAC Pharmacies that originate from civilian providers
- Providers may fax the completed form to (785)239-7487 or the patient may present this upon filling Lamisil®
- For questions on the use of this form, please call (785) 239-7619.
- This form and PA is only necessary for the treatment of onychomycosis. A copy of this form are available from our website: http://iach.amedd.army.mil/sections/clinics/pharmacyMain.asp

Step	Complete patient and physician information (Please print)				
1	Patient Name:	Physician Name:			
	Address:	Address:			
	Member #:	Phone #:			
Cton		Secure Fax #:			
Step	Why is terbinafine (Lamisil®) being prescribed?				
2	For treatment of onychomycosis of fingernails – proceed to Step 3.				
	For treatment of onychomycosis of toenails – proceed to Step 3.				
Step 3	Was the diagnosis of onychomycosis confirmed by a microbiological or histological test [KOH preparation, periodic acid Schiff (PAS) stain, or culture]?				
	Please note: Each 6 wk or 12 wk course of treatment requires confirmation of fungal infection using one of the above tests and submission of another PA request.				
	For fingerna daily.Yes	ail treatment, coverage approved for 6 weeks	of terbinafine 250mg once		
		treatment, coverage approved for 12 weeks o	f terbinafine 250mg once		
	☐ No Coverage not a	pproved.			
Step 4	I certify the above is correct and accurate to the best of my knowledge. Please sign and date.				
	Prescribing F	Physician's Signature	Date		

Approved by P&T Committee: July 2004

"Privacy Act Statement" AUTHORITY: 10 U.S.C. 3012 PRINCIPLE PURPOSE(S): To collect information regarding patient diagnosis and to gain access to patient medical record to conduct Medication Use Evaluation. ROUTINE USE(S): Used by Pharmacy staff to determine patient diagnosis and to conduct Medication Use Evaluation. VOLUNTARY: Voluntary, however, refusal to do so may preclude dispensing of medication.

	Site	Dosing	Cost/Regimen
Terbinafine	Fingernail	250mg once daily x 6 weeks	\$277
(Lamisil®)	Toenail	250mg once daily x 12 weeks	\$554

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Rationale for PA – Antifungals for the treatment of onychomycosis (fungal infection of the fingernails or toenails) include terbinafine (Lamisil®). Because of the potential side effects and requirements for liver function testing associated with systemic antifungal therapy, verifying the presence of a fungal infection prior to treatment is good clinical practice. A study published in CUTIS (1999;64:407-10) showed that as many as 35% of patients empirically diagnosed with onychomycosis did not have a fungal infection. Traumatic nail injuries (even just from wearing combat boots) can often visually appear as onychomycosis. Therefore, it is standard of care for all providers, including experts such as dermatologists, to use testing to confirm the fungal infection.

The FDA recommends:

- 1) Definitive diagnosis of a fungal infection
- 2) Pretreatment lab tests
- 3) Avoidance of these drugs in patients with acute or chronic liver disease.

Coverage for treatment of onychomycosis with terbinafine requires positive confirmation of a fungal infection with a microbiological or histological test [KOH preparation, periodic acid Schiff (PAS) stain, or culture].

Because it takes time for the nail to grow out following a course of systemic treatment for onychomycosis, re-treatment with systemic agents prior to 6 months is typically not necessary. Each course of treatment for onychomycosis requires confirmation of an active fungal infection and a separate prior authorization form.

The following criteria are identical to those established by the Department of Defense Pharmacy & Therapeutics (P&T) Committee for terbinafine (Lamisil®) obtained through TRICARE Pharmacies.

Prior Authorization Criteria for Terbinafine for the Treatment of Onychomycosis

Coverage **is NOT** provided for:

Treatment of onychomycosis *not* confirmed by a microbiological or histological test (KOH preparation, periodic acid Schiff stain (PAS stain), or culture).

Coverage is provided for:

- Treatment of onychomycosis confirmed by a microbiological or histological test (KOH preparation, periodic acid Schiff stain (PAS stain), or culture).
- Coverage is approved for 6 weeks for treatment of fingernail onychomycosis and 12 weeks for treatment of toenail onychomycosis.
- Treatment of fungal infection other than onychomycosis. Coverage approved for 12 months.

(Criteria for terbinafine PA approved at the IACH March 2007 P&T Committee)